REMARKS

Applicant respectfully requests reconsideration.

Claims 1, 10, 34, 42, 49, 53, 63, 69-71, 73, 84, 90, 107, 116 and 134-140 were previously pending in this application. Claims 1, 10, 34, 42, 49, 53, 73, 84, 90, 107 and 116 are withdrawn.

Claims 63, 71 and 134 are amended. Support for these amendments can be found at least on page 43 line 30 through to page 31 line 4. Claim 140 is cancelled. These amendments and cancellation are being made without prejudice or disclaimer. Applicant reserves the right to pursue the subject matter of the originally filed claims in one or more continuing applications.

Claims 63, 69-71 and 134-139 are pending for examination with claims 63 and 71 being independent claims. No new matter has been added.

Rejections under 35 U.S.C. §112, first paragraph

Written Description

Claims 63, 69-71 and 134-140 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. At the outset, Applicant notes it had previously faced and overcome a written description rejection. The Examiner has now made another written description rejection of essentially the same claims. Applicant has made good faith efforts to further prosecution of the pending claims, yet the Examiner appears to be carrying out prosecution in a piecemeal manner. Such piecemeal examination is discouraged by the USPTO which takes the position that "the examiner ordinarily should reject each claim on all valid grounds available." MPEP 707.07(g). The issuance of the Written Description Training Materials does not constitute new grounds of rejection, as these materials are not law. Applicant is entitled, at the very least, to proceed in the good faith belief that rejections that have been *overcome* will not be made again, particularly when the claims have remained essentially the same.

The Examiner has rejected the claims based on the scope of each genus of nucleic acids. The Examiner contends that the claimed nucleic acids are "highly variable because a significant number of structural and biological differences (exist) between genus members ... and each genus includes partial structures of SEQ ID NO:2 and SEQ ID NO:1, respectively". The Examiner further states that "the specification ... does not describe and define any structural

features, nucleotide sequences, and/or biological functions that are commonly possessed by members of each genus."

Applicant respectfully traverse in part. The claimed nucleic acids are defined both structurally and functionally. The functional features recited in the claims are attributable to the structural features also recited in the claims. However without conceding the Examiner's position and rather in the interest of expediting prosecution, Applicant has amended claims 63 and 71 to recite that the nucleic acids are at least 48 nucleotides in length. Support for this amendment can be found in the specification on page 43 line 30 through to page 44 line 4.

The Examiner has incorrectly concluded that the specification provides a single species within the claimed genus. The specification provides a number of species including SEQ ID NO:1 (55 nucleotide sequence lacking the 5 nucleotide motif TATTT), SEQ ID NO:16 (193 nucleotide sequence lacking the 5 nucleotide motif TATTT), SEQ ID NO:18 (48 nucleotide sequence lacking the 5 nucleotide motif TATTT), SUB sequences (sequences that substitute the 5 nucleotide motif TATTT with ATAAA including but not limited to those that are 53 nucleotides in length), sequences that substitute the 5 nucleotide motif TATTT with ACGTA, TATCG, TGCTG, AAACC, CGATC, GCTAT, TATGG, TATAA, AAAAA, TTTTT, CCCCC or GGGGG, and sequences that comprise nucleotides 9-38 of SEQ ID NO:1, among others.

With respect to claim 63, the nucleic acids include those that hybridize to a wild type ica promoter sequence (SEQ ID NO:2) under stringent conditions, and at least span and contain a mutation (i.e., an addition, a deletion or a substitution) in a region that corresponds to nucleotides 24-28 in the wild type promoter sequence of SEQ ID NO:2. The nucleic acids are at least 48 nucleotides in length. When operably linked to an ica nucleic acid, these nucleic acids enhance production of poly-N-acetyl glucosamine (PNAG).

The Examiner has incorrectly concluded that the nucleic acids within the claimed genus have "widely differing sequences". The nucleic acids, which are at least 48 nucleotides in length, possess sufficient homology to SEQ ID NO:2 to hybridize to that sequence under stringent hybridization. Hybridization under stringent conditions to a nucleic acid of known sequence is known in the art to identify structurally similar nucleic acids (i.e., nucleic acids of similar sequence). (See Written Description Training Materials, Revision 1, March 25, 2008, Example 6: DNA Hybridization.) In part, it is this homology to SEQ ID NO:2 that allows the

claimed nucleic acids to act as promoters when operably linked to an ica nucleic acid, as recited in the claims. The ability of the claimed nucleic acids to enhance PNAG production is a result of possessing a mutation in a defined 5 nucleotide region (i.e., the region between and including nucleotides 24 and 28 of SEQ ID NO:2). That mutation is also defined in the claims as an addition, a deletion or a substitution at at least 2 of the 5 nucleotides in this region. In view of the recognized correlation between structure and function of the claimed nucleic acids, those of ordinary skill in the art will be able to identify which of the nucleic acids (having a minimum length of 48 nucleotides) that hybridize to SEQ ID NO:2 and possess the requisite mutation in the 5 nucleotide region will enhance PNAG production.

With respect to claim 71, the nucleic acids are fragments of a mutant ica promoter (i.e., SEQ ID NO:1), and they include nucleotides 23 and 24 of SEQ ID NO:1. These nucleic acids function as promoters and, when operably linked to an ica nucleic acid, they also enhance production of PNAG. SEQ ID NO:1 is 55 nucleotides in length and the claimed nucleic acids are at least 48 nucleotides in length. Therefore, the claimed nucleic acids share at least 87% identity with SEQ ID NO:1 (i.e., 48 of the 55 nucleotides of SEQ ID NO:1 are present in each of the claimed nucleic acids). Each of the claimed nucleic acids also share the mutation of SEQ ID NO:1 (i.e., the deletion of TATTT). The ability to enhance PNAG production is attributable to this 5 nucleotide mutation. Therefore, each of the nucleic acids as claimed possess the structural characteristics that impart their functional characteristics. One of ordinary skill will be able to envision the fragments embraced by claim 71.

In view of the foregoing, Applicant submits that it was in possession of the claimed subject matter and that this would be recognized by those of ordinary skill in the art based on the disclosed species and the recognized structure-function relationship of the claimed nucleic acids.

Reconsideration and withdrawal of this rejection is respectfully requested.

Enablement

Claims 63, 69-71 and 134-140 are rejected under 35 U.S.C. §112, first paragraph, according to the Examiner, because the specification "does not reasonably provide enablement for any nucleic acid molecule or any complement thereof as recited in claim 63, and any nucleic acid molecule or any complement thereof as recited in claim 71". The Examiner however

considers that the specification enables an isolated nucleic acid molecule comprising SEQ ID NO:2 or a full complement thereof, and an isolated nucleic acid molecule comprising SEQ ID NO:1 or a full complement thereof. Respectfully, SEQ ID NO:2 (and its complement) corresponds to a wild type ica promoter sequence which is not embraced by the claims. Applicant clarified this in its last response yet the Examiner continues to maintain that SEQ ID NO:2 is enabled and thus embraced by the claims. Applicant requests clarification or correction by the Examiner.

Applicant notes that the prior Office Action set forth an enablement rejection based solely on the meaning of "ica locus" and "ica nucleic acid" and uncertainty regarding the "specific enzyme and/or proteins are enhanced (sic) that result in the overproduction of any polysaccharides". Applicant made a good faith effort to address that rejection and presumably had overcome those bases as they are not reiterated in the present rejection. However, the Examiner continues to assert an enablement rejection on grounds that were not set forth in the prior Office Action and that are not a result of an amendment to the claims. In other words, the current rejection could have been made previously but it was not. Applicant again stresses that it has made good faith efforts to further prosecution of the pending claims, yet the Examiner appears to be carrying out prosecution in a piecemeal manner. This is inconsistent with USPTO policy. MPEP 707.07(g). Applicant is entitled to proceed in the good faith belief that rejections are made fully, outlining all possible grounds, so that Applicant can address and overcome the rejections in a timely manner rather than over the course of several years as the Examiner continues to change the rationale for rejecting claims that remain essentially the same. MPEP 707.07(g).

The Examiner states that "the specification does not provide the guidance, prediction, and working examples showing a correlation between any structure, nucleotide composition, and nucleotide sequence of the nucleic acid molecules as claimed and its biological function such as enhancing production of poly-N-acetyl glucosamine". Applicant traverses. The specification teaches the nucleotide sequences of SEQ ID NO:1 and SEQ ID NO:2. It further identifies the 5 nucleotide region within SEQ ID NO:2 which is to be mutated in order to effect enhanced production of PNAG. It teaches the types of mutations that can be made in this 5 nucleotide region (i.e., additions, deletions or substitutions). It provides species of the claimed nucleic acids

including SEQ ID NO:1 (55 nucleotide sequence lacking the 5 nucleotide motif TATTT), SEQ ID NO:16 (193 nucleotide sequence lacking the 5 nucleotide motif TATTT), SEQ ID NO:18 (48 nucleotide sequence lacking the 5 nucleotide motif TATTT), SUB sequences (sequences that substitute the 5 nucleotide motif TATTT with ATAAA including but not limited to those that are 53 nucleotides in length), sequences that substitute the 5 nucleotide motif TATTT with ACGTA, TATCG, TGCTG, AAACC, CGATC, GCTAT, TATGG, TATAA, AAAAA, TTTTT, CCCCC or GGGGG, and sequences that comprise nucleotides 9-38 of SEQ ID NO:1, among others. Thus, the specification provides guidance and working examples showing the correlation between structure and function of the claimed nucleic acids.

The Examiner further bases the rejection on the recitation of "complement" and asserts incorrectly that it encompasses fragments. Complement is an art-recognized term that refers to a nucleic acid having a sequence that is complementary to another nucleic acid. The term does not infer nucleic acids of differing length, and thus it does not encompass fragments. This term was present in the original claims and this is the first time that the Examiner has raised an issue with it.

Based on this incorrect interpretation of the term "complements," the Examiner further states that the claims may encompass dinucleotide fragments. In view of the amendment of the claims to recite nucleic acids (and complements thereof) that are at least 48 nucleotides in length, this ground of rejection is rendered moot.

Applicant submits that the subject matter of the rejected claims can be practiced without undue experimentation. The nucleic acids are structurally and functionally defined, and importantly there exists a correlation between their structural and functional attributes, as taught by the specification. The rejected claims are therefore enabled.

Reconsideration and withdrawal of this rejection is respectfully requested.

Rejection under 35 U.S.C. §112, second paragraph

Claims 63, 69-71 and 134-140 are rejected under 35 U.S.C. §112 as being indefinite for failing to particularly point out and distinctly claim the subject matter applicant regards as the invention.

The Examiner considers claims 63 and 71 (from which the remaining rejected claims depend) vague and indefinite for reciting the phrase "*ica* nucleic acid comprising nucleotides 2330-5745 of SEQ ID NO: 3 (GenBank Accession No. AF086783)". In the interest of expediting prosecution, Applicant has amended these claims to delete the recitation of GenBank Accession No. AF086783 which was included as an identifier for SEQ ID NO:3. In this respect, the claims now refer only to SEQ ID NO:3, a sequence that was part of the specification at the time of filing.

The Examiner further considers claim 63 indefinite because "it is not clear if SEQ ID NO:2 or any other nucleic acid that hybridizes to SEQ ID NO:2 is being claimed". Applicant traverses. SEQ ID NO:2 is a nucleotide sequence of a wild type ica locus promoter, and it is not being claimed. Rather, the claims embrace nucleic acids that have mutations in a particular region of SEQ ID NO:2. That region corresponds to nucleotides 24-28 of SEQ ID NO:2. The mutations may be additions, deletions or substitutions of two or more nucleotides in this region. Thus, claim 63 embraces nucleic acids that hybridize under stringent conditions to SEQ ID NO:2 and which span a region of SEQ ID NO:2 corresponding to nucleotides 23-29 but which harbor mutation between those nucleotides. The nucleic acids are further functionally defined as enhancing production of PNAG when operably linked to an *ica* nucleic acid relative to the level of production when the wild type sequence (SEQ ID NO:2) is operably linked to the ica nucleic acid. The ica nucleic acid comprises nucleotides 2330-5745 of SEQ ID NO: 3 which encode IcaA, IcaD, IcaB and IcaC.

One of ordinary skill in the art would understand the metes and bounds of the claims and thus the claims are definite.

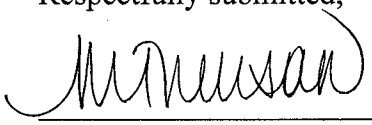
Reconsideration and withdrawal of this rejection is respectfully requested.

CONCLUSION

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,



Maria A. Trevisan
Registration No.: 48,207
WOLF, GREENFIELD & SACKS, P.C.
Federal Reserve Plaza
600 Atlantic Avenue
Boston, Massachusetts 02210-2206
617.646.8000

Date: November 5, 2008
x11.06.08